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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/878,168	06/18/1997	AVI J. ASHKENAZI	P1110	6813
7590 12/23/2005 DIANE L MARSCHANG 1 DNA WAY SOUTH SAN FRANCISCO, CA 94080			EXAMINER KAUFMAN, CLAIRE M	
			ART UNIT 1646	PAPER NUMBER

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

08/878,168

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-11, 15-21 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-21 and 30-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1646

### **DETAILED ACTION**

Prosecution is reopened and the suspension and indication of allowability is withdrawn in view of the rejections set forth below.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated Apo-2DcR polypeptide having at least 80% amino acid sequence identity with native sequence Apo-2DcR polypeptide comprising amino acid residues of 1-259 of SEQ ID NO:1, which isolated Apo-2DcR polypeptide binds Apo-2 ligand (Apo-2L), does not reasonably provide enablement for an isolated Apo-2DcR polypeptide having at least 80% amino acid sequence identity to SEQ ID NO:1 which does not bind Apo-2L. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The claims are broadly drawn to an "isolated Apo-2DcR polypeptide having at least 80% amino acid sequence identity...to SEQ ID NO:1" without limitation of function. Applicants found that native sequence Apo-2DcR binds Apo-2L (p. 8, lines 15-16), and three Apo-2L receptors, Apo-2, Apo-2DcR and DR4, all map to chromosome 8p21 (p. 75, lines 13-14). However, even with this knowledge, one skilled in the art would not know how to use a polypeptide 80% identical to SEQ ID NO:1 if it too did not bind Apo-2L. The specification provides no guidance for or examples of using such a non-binding polypeptide. The claims are not commensurate in scope with the teachings of the specification or prior art. It would require undue experimentation to use the invention as broadly claimed.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1646

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim 1-11, 15-21 and 30-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Patent 6,261,801 (Wei et al.).

US Patent 6,261,801 teaches “TRID” or “tumor necrosis factor receptor 5” (“TNFR-5”) with the amino acid sequence of SEQ ID NO:2, which has the same sequence as the sequence of SEQ ID NO:1 of the instant application. Also taught (col. 1, lines 10-16) is the ability of TRID to bind TRAIL (also known as Apo-2 ligand, col. 3, lines 4-12). Vectors and host cells, including E. coli, yeast and CHO cells, comprising or expressing TRID or at least the extracellular domain thereof are taught in col. 14, line 27-36, and col. 33, line 30- col. 40, line 26. Chimeric proteins including those comprising an IgG sequence are taught in col. 21, lines 62- col. 22, line 10. Also taught are chimeric proteins comprising an epitope tag of hemagglutinin fragment (HA) to allow easy detection and recovery of the recombinantly produced protein with an antibody that recognizes the HA epitope (col. 37, line 55- col. 38, line 6).

This rejection has been reintroduced even though it was initially withdrawn in the Office action mailed 06/03/03 in view of Applicant’s arguments. The reasons it is now being applied is that the Examiner has become aware of the basis for an enabling disclosure in the priority documents to which US 6,261,801 claims priority, therefore providing the patent with an effective filing date earlier than the instant application’s. That is, in the patent’s earliest priority application, 60/035,496, it was established that soluble forms of TNFR-5 receptor (renamed TRID in later filed application 60/054,885) can function as antagonists, and antagonists are capable of inhibiting apoptosis (p. 51, lines 24-29 and p. 54, lines 28-30). Additionally disclosed is the administration of an antagonist to reduce selective killing of CD4 T-lymphocytes in HIV+

Art Unit: 1646

individuals (p. 55, line 27- p. 56, line 17). The latter antagonist role is supported by art (e.g., Miura et al., J. Exp. Med. 193(5):651-9, 2001).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (571) 272-0873. Dr. Kaufman can generally be reached Monday, Tuesday, Thursday and Friday from 9:30AM to 2:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (571) 272-0829.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Official papers filed by fax should be directed to (571) 273-8300. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

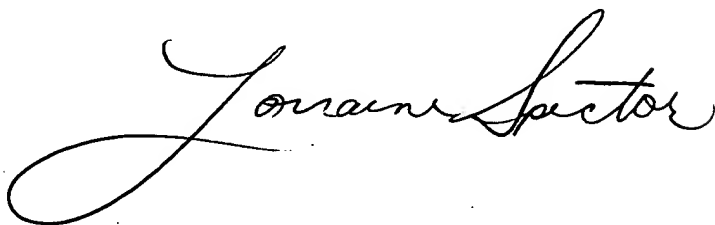
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Claire M. Kaufman, Ph.D.



Patent Examiner, Art Unit 1646

December 20, 2005



**LORRAINE SPECTOR  
PRIMARY EXAMINER**